Appl. No. 09/361,542
Atty. Docket No. 7247M
Amdt. dated September 12, 2007
Reply to Office Action of April 12, 2007
Customer No. 27752

REMARKS

Claim Status

Claims 36, 38, 41-44, 46 and 48 are pending. Claims 36 and 43 have been amended to recite that the liquid aqueous composistion of the present invention forms a gel-like mixture upon contact with a mucosal surface, thereby retaining the composition thereon. Support for the amendments is found for example at page 2, lines 10-21, page 4, lines 28-35, page, and page 5, lines 9-37.

Claims 1-35, 37, 39-40, 45 and 47 were previously canceled without prejudice.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a) Over US Patents 5,589,160 and 5,658,553

Claims 36, 38, 41-44, 46, and 48 are rejected under 35 USC §103(a) as being unpatentable over either US Patent 5,112,604 ("Beaurline") alone. The Applicant respectfully traverses the rejections to the extent they apply to the claims as now amended.

The Examiner asserts that Beaurline teaches oral, aqueous suspension formulations comprising a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water, and other components.

In response to the Applicant's previous arguments the Examiner asserts that, although Beaurline nowhere teaches or discloses more than 2% silicon dioxide, the Applicant has not shown that Beaurline states that more than 2% silicon dioxide should not be employed.

In addition, the Examiner asserts that while Beaurline does not teach mucoretention, because Beaurline discloses 2% silicon dioxide, the compositions of Beaurline must therefore be mucoretentive, and that the Applicant has not shown that Beaurline states that the compositions disclosed therein do not form a gel-like mixture.

Furthermore, the Examiner asserts that the method of Claim 36 only recites a *method* of administering an active agent, but that the *composition* forms a gel-like mixture, and that therefore, the formation of the gel-like mixture of the composition is

taught by Beaurline because the Applicant has not shown that Beaurline specifically teaches that the compositions disclosed therein do not form gel-like mixtures.

Finally, the Examiner asserts that the term "about" allows for a standard variation of at least 10%.

The Applicant respectfully traverses the rejections, as they may apply to the Claims as amended.

Claim 36, as amended, recites a method of administering an active agent at one or more of the esophagus, stomach, and small intestine by swallowing a safe and effective amount of a liquid aqueous mucoretentive composition...and wherein the liquid aqueous mucoretentive composition forms a gel-like mixture upon contact with a mucosal surface, thereby retaining said composition thereon.

Therefore, the method of Claim 36 includes not only a method of administering an active agent, but also includes *retaining* the composition on a mucosal surface.

Beaurline does not teach, suggest, or provide any motivation, indication, or expectation of success to lead one of ordinary creative skill in the art to any need or reason for administering *and retaining* a composition on a mucosal surface. Beaurline does not anywhere teach or suggest a liquid aqueous composition that forms a gel-like mixture when in contact with a mucosal surface, and is retained thereon.

With respect to the Examiner's assertions, an Applicant, even under the modified, and possibly broader obviousness analysis of *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007), is not required to show explicit teaching away show non-obviousness. However, the Examiner attempts to require a showing of explicit teaching away. The Examiner states that the Applicant has not shown that Beaurline specifically teaches that the compositions disclosed therein do not form gel-like mixtures, that the Applicant has not shown that the compositions of Beaurline are not mucoadhesive, and that the Appliant has not shown that Beaurline teaches that more than 2% colloidal silicon dioxide should not be employed. The Applicant is not required to show explicit teaching away.

With respect to the composition of Claims 36 and 43, the compositions of Beaurline require: 0.1 to 15% by weight of a particulate medicament with a particle size of less than about 150 μm, about 0.02 to about 5% b weight of a wetting agent, about 0.02 to about 0.10% by weight of a hydrocolloid gum, about 0.2 to about 2% by weight of

colloidal silicon dioxide, about 0.1 to about 0.3% of an antifoaming agent, a carbohydrate, and water. See column 2, lines 6-18 for wetting agent; 19-26 for hydrocolloid gum; 26-34 for silicon dioxide; 35-39 for antifoaming agent; 40-41 for carbohydrate and water; and column 3, lines 9-15 for particulate medicament.

The Applicant's composition does not require all of the elements of the Beaurline composition, for example, a hydrocolloid gum or an antifoaming agent. Therefore, although the Applicant discloses that an effective amount of the particulate component of the Applicant's composition can provide mucoadhesive benefit, and discloses 2% of the particulate component, the 'effective amount' used to provide the mucoadhesive benefit is taken in context with the Applicant's entire composition. There is no indication, whatsoever, simply because Beaurline teaches compositions containing up to 2% colloidal silicon dioxide, that the silicon dioxide as used in the compositions of Beaurline as a whole, would provide mucoadhesive properties to the compositions, would be retained on a mucosal surface, or would form a gel-like mixture when in contact with a mucosal surface.

There is nothing at all in Beaurline that suggests that the composition of Beaurline, as a whole, would be, or would be sought to be, mucoretentive or form a gel-like mixture upon contact with a mucosal surface.

Even considering the common sense of a person of ordinary creative skill in the art, and the likely formulations such a person might try in order to solve the problem addressed by Beaurline in order to produce a suspension that stays suspended uniformly for a period of at least 90 days, there is nothing in Beaurline that would suggest or provide any expectation of success to such a person to create a liquid aqueous mucoretentive composition that is retained on a mucosal surface via forming a gel-like mixture upon contact with a mucosal surface.

With respect to the Examiner's assertions regarding the term "about", the Examiner has provided no citation or authority whatsoever to support the assertion that the term "about" allows for a standard variation of at least 10%. The Applicant is not aware of any case law that establishes a blanket standard variation of at least 10% for all uses of the term "about", nor does the MPEP at section 2173.05(b)A, which discusses the term "about", provide any such standard.

The term "about" should be given its ordinary and accepted meaning of "approximately" unless the patentee clearly redefines "about" in the specification. See

Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc. 395 F.3d 1364, 73 USPQ 2d 1641m 1648 (Fed. Cir 2005). As the examiner has provided no citation of any authority, there is no basis for the Examiner's arbitrary 10% "standard variation". Therefore, the Examiner's rejection on the basis that the term "about" allows for a standard variation of at least 10% is unsupported, without basis, and can not stand.

Therefore, the claimed invention is unobvious over the cited document and the Applicant respectfully requests that the rejections be withdrawn.

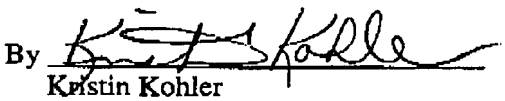
Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC §103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form for allowance and to distinguish the invention as now claimed from the applied document. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of all pending Claims is respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By 
Kristin Kohler
Registration No. 41,907
(513) 622-3371

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Customer No. 27752